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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,199	10/10/2003	Peter Hermentin	06478.1495	1253
22852	7590	11/29/2006		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/682,199	HERMENTIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on September 5, 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-25,27,28,30,31,33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-25,27,28,30,31,33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1641

## DETAILED ACTION

Examiner acknowledges Applicants' reply, filed September 5, 2006. Currently, claims 16-25, 27-28, 30-31, 33 and 35 are under examination.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-24, 27-28, 30-31, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shainoff, *Electrophoresis and direct immunoprobng on glyoxal agarose*, in ADVANCES IN ELECTROPHORESIS, Vol. 6, VCH Publishers, pp. 65-176 (1993), in view of Bhat & Nagineni, 170 ANAL. BIOCHEM 105 (1988).

Shainoff teaches a method for the determination of multimers of multimer-forming proteins by gel electrophoresis, comprising:

fractionating a sample containing von Willebrand factor (see p. 78, left column, 2.1.1.1 Gel concentrations, first paragraph) or fibrinogen (see p. 66, left column, 1.1 Development of glyoxyl

Art Unit: 1641

agarose and composites, first paragraph) into multimer bands by electrophoresis using a continuous, homogeneous (see Table 1) agarose gel (see Title);

visualizing multimer bands by a dye in the gel (see p. 98, left column, 2.7 General protein staining);

optionally, quantifying the dyed multimer bands (see p. 98, right column, 2.8 Mounting, photographing and scanning gels, first paragraph, "densitometers").

Shainoff does not describe "submarine" electrophoresis.

However, Bhat & Nagineni describe the use of "submarine" electrophoresis for resolving proteins (see Title).

It would have been obvious for a person of ordinary skill in the art to replace the electrophoretic protocol of Shainoff with a "submarine" method because Bhat & Nagineni discovered that the "submarine" method allows for stacking of multiple gels allowing for multiple simultaneous runs (see Abstract).

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Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shainoff, *Electrophoresis and direct immunoprobng on glyoxal agarose*, in ADVANCES IN ELECTROPHORESIS, Vol. 6, VCH Publishers, pp. 65-176 (1993), and Bhat & Nagineni, 170 ANAL. BIOCHEM 105 (1988), as applied to claim 16 and 24, and further in view of Perrella & Denisov, 259 METHODS ENZYMOL. 468 (1995).

Shainoff and Bhat & Nagineni describe a method for the determination of multimers as substantially described, *supra*, and incorporated herein.

Art Unit: 1641

Shainoff and Bhat & Nagineni do not describe a method wherein electrophoresis is carried out between 8-12°C.

However, Perrella & Denisov describe the use of temperature to modify electrophoresis (see Title).

It would have been obvious for a person of ordinary skill in the art to modify the electrophoretic protocol of Shainoff and Bhat & Nagineni by modifying temperature because Perrella & Denisov teach that the use of temperature to modify electrophoresis allows for probing of "intermediate stages of ligation" and "quaternary structural changes" (see first paragraph).

**Response to Arguments**

In prior Office Action, claims 16-24, 27-28, 30-31, 33 and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shainoff, *Electrophoresis and direct immunoprobings on glyoxal agarose*, in ADVANCES IN ELECTROPHORESIS, Vol. 6, VCH Publishers, pp. 65-176 (1993), in view of Bhat & Nagineni, 170 ANAL. BIOCHEM 105 (1988). Claim 25 was rejected under 35 U.S.C. 103(a) as being unpatentable over Shainoff, *Electrophoresis and direct immunoprobings on glyoxal agarose*, in ADVANCES IN ELECTROPHORESIS, Vol. 6, VCH Publishers, pp. 65-176 (1993), and Bhat & Nagineni, 170 ANAL. BIOCHEM 105 (1988), as applied to claim 16 and 24, and further in view of Perrella & Denisov, 259 METHODS ENZYMOL. 468 (1995).

In response, Applicants potentially argue the following:

1. Shainoff does not teach "agarose" gels because "glyoxal agarose" is not the same material as "agarose" (see Applicants' reply, p. 7, second full paragraph; see also, paragraph bridging pp. 8-9).
2. Neither Shainoff nor Bhat & Nagineni describe gels "free of lumps" (see Applicants' reply, paragraph bridging pp. 8-9 and p. 9, first full paragraph).
3. Shainoff teaches away from Applicants' invention because Shainoff does not teach "agarose" gels (see Applicants' reply, p. 7, second full paragraph, last sentence).
4. Bhat & Nagineni do not exclude the possibility of using Shainoff's teachings with the teachings of Bhat & Nagineni (see Applicants' reply, paragraph bridging pp. 7-8, first sentence, "Bhat & Nagineni [do] not motivate one of ordinary skill in the art to turn against Shainoff's advice[...]") (paraphrasing mine).
5. Bhat & Nagineni provide no motivation to conduct a fibrinogen separation using agarose because Bhat & Nagineni do not teach separation of fibrinogen or vWF (see Applicants' reply, paragraph bridging pp. 7-8, first sentence, "Bhat & Nagineni [do] not motivate one of ordinary skill in the art

Art Unit: 1641

to[...] conduct a fibrinogen separation using agarose because [Bhat & Nagineni] does not teach separation of fibrinogen and von Willebrand factor") (liberal paraphrasing mine).

6. Bhat & Nagineni describe "a different type of electrophoresis experiment with different issues in terms of resolution and visualization than Applicants' multimer separation procedure" (see Applicants' reply, sentence bridging pp. 7-8).
7. The teachings of Perrella & Denisov are not in Applicants' field of endeavor (see Applicants' reply, p. 10, first full paragraph).

Applicants' arguments have been carefully considered but are not persuasive.

With respect to 1) and 3), Shainoff describes gels made of either "agarose" or "glyoxal agarose", or both. For example, Shainoff experimented with gels made of "regular agarose" (see p. 67, line 14, "regular agarose"). In addition, Shainoff experimented with "composite gels" made with regular agarose (see p. 72, lines 5-6 of the third paragraph, "composite of glyoxyl agarose with[...] blended with regular agarose") (paraphrasing mine).<sup>1</sup>

With respect to 2), Examiner is unable to discern any lumps in any two-dimensional black and white depiction of any gel in either Shainoff or Bhat & Nagineni. Thus, Shainoff or Bhat & Nagineni appear lump-free.

With respect to 3), 5), 6) and 7), the test for obviousness is not whether the structural features of either Shainoff or Bhat & Nagineni may be bodily incorporated into each other or Applicants' invention, nor is the test whether the claimed invention must be expressly suggested in any one or all of the references.

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<sup>1</sup> According to M.P.E.P. §2123, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

Art Unit: 1641

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). One cannot show nonobviousness by attacking the teachings of Shainoff and Bhat & Nagineni individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With respect to 4), Examiner agrees with Applicants' potential argument. If Examiner's paraphrasing, *supra*, is in fact accurate, Applicants' argument amounts to a validation of the propriety of this rejection. Clarification of Applicants' argument may be required.

With respect to 7), Examiner respectfully disagrees with Applicants' assertion that the teachings of Perrella & Denisov are not in Applicants' field of endeavor. Applicants' invention is directed to a method of analyzing multimeric proteins using gel electrophoresis. Perrella & Denisov describe a particularly useful method of analyzing multimeric proteins using gel electrophoresis, which allows for probing of "intermediate stages of ligation" and "quaternary structural changes" (see first paragraph).



Art Unit: 1641

**Conclusion**

No claims are allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci  
Examiner  
Art Unit 1641

djv

  
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